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SENNIGER POWERS LLP 100 NORTH BROADWAY 17TH FLOOR ST LOUIS, MO 63102			SRIVASTAVA, KAILASH C	
			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspatents@senniger.com

Office Action Summary	Application No. 10/590,446	Applicant(s) FORGACS ET AL.	
	Examiner Kailash C. Srivastava	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 October 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11-17 and 52-66 is/are pending in the application.
- 4a) Of the above claim(s) 1-9 and 11-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 52-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1/22/2008 & 5/25/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Amendment and response filed 11 October 2010 to Office Action with election/restriction requirement mailed 09 August 2010 is acknowledged and entered.
2. Also acknowledged is the response and amendment to Claims filed 20 August 2010 to Office Action with election/restriction requirement mailed 09 August 2010. An Office Action to said response and amendment filed 20 August 2010 was not mailed, however, in accordance with Interview Summaries mailed respectively on 09 August and 13 October 2010 already of record.
3. Regarding Claims, 67-84, Applicants have already cancelled said claims on record. Accordingly, said claims can not be considered.

Claims Status

4. According to the amendment filed 11 October 2010, following is the current Claims status:
 - Claims 10, 18-51 and 67-84 have currently been cancelled.
 - Claims 1 and 52 have currently been amended.
 - Claims 1-9, 11-17 and 52-66 are currently pending.

Restriction/Election

5. Applicants' election with traverse of Group III invention encompassing Claims 52-66 drawn to a three dimensional layered structure comprising at least one layer of a biocompatible matrix and a plurality of cell aggregates, each cell aggregate comprising a plurality of living cells, wherein cell aggregates are embedded in the at least one layer of biocompatible matrix in a non-random pre-determined pattern, i.e., a composition; filed 11 October 2010 to the Office Action with election/restriction requirement mailed 09 August 2010 is acknowledged and entered.

The traversal is on the grounds of recital of PCT Rule 13, 37 C.F.R. §1.475, M.P.E.P. §1893.03(d) and 37 C.F.R. §1.475(b) and the argument that the Koibuchi article cited in the

Office Action issued 09 August 2010 recited *supra* does not suggest the technical contribution that the “Applicants are the first to conceive of and enable production of desired three-dimensional engineered tissue structures by embedding a plurality of cell aggregates in a biocompatible matrix according to a pre-determined pattern so the cell aggregates will self-assemble in to the desired three-dimensional structure (See, Remarks filed 10/11/2010, Page 7, Lines 6-11, 26-27 and the discussion at remainder of Pages 6-8 of the Remarks filed 10/11/2010). Applicants agree, however, Office has a mandate to give the broadest possible interpretation, but argue that said interpretation of claims during the prosecution should be consistent with the interpretation (of) those skilled in the art, which in Applicants’ opinion is not the case with the pre-determined pattern discussed in Libera et al (US Patent Application Publication 2003/0153078 A1 published 14 August 2003) methods and compositions (Abstract, Example 3).

In response to Applicants’ arguments/discussion cited *supra*:

(i) please note the Examiner is also a person of ordinary skill because the examiners also have general and specific knowledge of the technical subject matter and the pertinent scientific and technical literature presented in front of them;

(ii), without detailing too much, aside from Libera et al., already of record; there are a number of publications describing the claimed composition in instantly presented Claims 52-66 , See examples below);

Nickerson et al. 2001. Three-Dimensional Tissue Assemblies: Novel Models for the Study of Salmonella enterica Serovar Typhimurium Pathogenesis. Infection and Immunity, Volume 69, Number 11, Pages 7106-7120.

Yamauchi et al. (2003. A Three-dimensional Cell Culture Model for Bovine Endometrium: Regeneration of a Multicellular Spheroid Using Ascorbate. Placenta, Volume 24, Pages 258–269).

Dai et al. (1996. Fibroblast Aggregation by Suspension with Conjugates of Poly(ethylene glycol) and RGD, Biotechnology and Bioengineering, Volume 50, Page. 349-356, item 4, Applicants’ IDS filed 1-22-2008).

Thus, the prior art clearly contributes arranging cell aggregates to a non-random predetermined pattern. Accordingly, the pertinent prior art as one of ordinary skill in said art would be aware discloses the instantly alleged special technical feature recited in Claims 52-66.

Applicants' arguments recited supra have been fully and carefully considered, but are not persuasive for the reasons of record at pages 3-5, items 8- 9 of the Office Action mailed 09 August 2010. Therefore, the restriction requirement is still deemed proper and is made FINAL.

Accordingly, Claims 1-9 and 11-17 are withdrawn from further consideration as being directed to a non-elected invention. See 37 C.F.R. §1.142(b) and M.P.E.P. § 821.03.

6. Claims 52-66 are examined on merits.

Priority

7. Claim for domestic priority under 35 U.S.C. §119(e) to Provisional U.S. Application Serial Number 60/547, 161 filed 24 February 2004 is acknowledged.

8. Claim for domestic priority under 35 U.S.C. §119(e) to PCT/US05/05735 filed 24 February 2005 is acknowledged.

Information Disclosure Statement

9. Information Disclosure Statements (i.e., IDSs) filed respectively on 22 January 2008 and 25 May 2010 are acknowledged, made of record, considered and duly signed copies of USPTO Form SB (08) are enclosed with the instant Office Action.

Claims Objected

10. Claims 53-63 and 66 objected to because of the following informalities:

Claims 53-63 and 66 are objected to because at Line one of each one of the cited Claims, before the word "wherein" a --, -- should be inserted.

Appropriate correction is required.

Claim Rejections - 35 USC §102

11. The following are quotations of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 52-53, 56, 58 and 62-63 are rejected under 35 U.S.C. §102(b) as anticipated by Furukawa et al (2001. Tissue-engineered skin using aggregates of normal human skin fibroblasts and biodegradable material J Artif. Organs, Volume 4, Pages 353-356).

Claims 52-53, 56, 58 and 62-63 claim a three dimensional layered structure comprising:

- ⇒ at least one layer of a biocompatible matrix (Claim 52);
- ⇒ a plurality of uniformly shaped and sized (Claim 53) spherical (Claim 56) cell aggregates, each comprising a plurality of living cells (Claim 52) of a single type (Claim 58);
- ⇒ said cell aggregates are embedded in a non-random predetermined pattern in at least one layer of said biocompatible matrix (Claim 52);
- ⇒ said biocompatible matrix is selected from the group consisting of: gels that are thermo-reversible, photosensitive, pH sensitive, cell specific or combinations thereof (Claim 62);
- ⇒ at least one layer of a biocompatible matrix comprises at least two different types of biocompatible matrices (Claim 63).

The three dimensional layered structure claimed in instantly presented Claims 52-53, 56, 58 and 62-63 is interpreted to be a composition comprised of different components.

Furukawa et al., teach three dimensional, high cell density aggregates (i.e., spheroids) comprised of human skin fibroblasts (Page 353, Column 1 Abstract, Lines 13-15, 22-23), wherein the aggregates are trapped in a matrix comprised of polyglycolic acid coated with type I collagen (Abstract at Page 353, Column 2 Lines 9-10; Page 354, Column 2, Lines 34-42, 56-57 and 61-63; Figures 1 and 2). Furukawa et al., additionally teach that the aggregates were grown in scaffold comprised of polyglycolic acid coated with type I collagen placed in 6-welled page (Page 354, Column 1, Lines 50-51).

Please note, Furukawa et al., teach three dimensional structure, i.e., spheroid) grown in a non-random pre-determined pattern embedded in layers of polyglycolic acid (i.e., at least one layer of a biocompatible matrix), said spheroids comprised of human skin fibroblasts (i.e., only one type of plurality of living cells). Thus, Furukawa et al., teach each of the limitations in Claim 52, because said aggregates are grown in a scaffold comprised in 6 wellled dish (a non-random pre-determined pattern). Furokawa et al., further teach smooth and round shape of said aggregates (Abstract, Page 353, Column 1, Lines 26-27) which is the limitation in Claim 53. Since said aggregates are spheroids, they are spherical shaped, i.e., limitation in Claim 56; and comprise only human skin fibroblasts, the living cells are of a single type (i.e., limitation in Claim 58). Said scaffold's matrix is polyglycolic acid and collagen, both of which are biocompatible matrices and are each thermo-reversible (i.e., polyglycolic acid and collagen) and pH sensitive (i.e., collagen), which are the limitations in instantly presented Claim 62. Furthermore, the scaffold in which the aggregates are embedded is comprised of a biocompatible matrix layer comprised of two different biocompatible matrices (i.e., polyglycolic acid and collagen Type I), which is the limitation in instant Claim 63.

Thus, as illustrated in the discussion supra, Furukawa et al., teach each and every limitation presented in instant Claims 52-53, 56, 58 and 62-63.

Therefore, the reference is deemed to anticipate the instantly recited Claims 52-53, 56, 58 and 62-63.

Claim Rejections - 35 USC §103

13. The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 52-53 and 56-66 are rejected under 35 U.S.C. §103 (a) as obvious over combined teachings from Furukawa et al. (2001. Tissue-engineered skin using aggregates of normal human skin fibroblasts and biodegradable material J Artif. Organs, Volume 4, Pages 353-356) in view of Boland et al. (US 2004/0237822 A1) and Roth et al. (2004. Inkjet printing for high-throughput cell patterning. Biomaterials, Volume 25, Pages 3707–3715).

Claims 52-53 and 56-63 claim a three dimensional layered structure comprising:

- ⇒ at least one layer of a biocompatible matrix (Claim 52);
- ⇒ a plurality of uniformly shaped and sized (Claim 53) spherical (Claim 56) cell aggregates, each comprising a plurality of living cells (Claim 52) of a single type (Claim 58);
- ⇒ said cell aggregates are embedded in a non-random predetermined pattern in at least one layer of said biocompatible matrix (Claim 52);
- ⇒ said cell aggregates are about 100µm to about 600µm in diameter (Claim 57);
- ⇒ each of said aggregate comprises plurality of living cells of two different types designated as of first type and second type as claimed in Claim 59;
- ⇒ plurality of said aggregates comprise plurality of living cells of two different types designated as of first type and second type as claimed in Claim 60;

- ⇒ said biocompatible matrix is about 100 μ m to about 600 μ m thick (Claim 61);
- ⇒ said biocompatible matrix is selected from the group consisting of: gels that are thermo-reversible, photosensitive, pH sensitive, cell specific or combinations thereof (Claim 62);
- ⇒ at least one layer of a biocompatible matrix comprises at least two different types of biocompatible matrices (Claim 63);
- ⇒ said biocompatible matrix is present as two separate layers and cell aggregates are embedded in each of the two biocompatible matrix layers (Claim 64);
- ⇒ said biocompatible matrix in Claim 64 is present at least as one additional layer and cell aggregates are embedded in said at least one additional layer (Claim 65);
and
- ⇒ said biocompatible matrix present in first layer is of a different type than that in the second layer (Claim 66).

The three dimensional layered structure claimed in instantly presented Claims 52-53, 56, 58 and 62-66 is interpreted to be a composition comprised of different components.

Regarding Claims 52-53 and 56-66, Furukawa et al.'s teachings have been discussed supra. Furukawa et al., however, are silent regarding diameter of said aggregates (i.e., limitation of Claim 57), thickness of biocompatible matrix (i.e., limitation of Claim 61) and each of said aggregates or plurality of aggregates comprising plurality of living cells of two different types (i.e., limitations in Claims 59-60).

Boland et al., teach:

- an array of viable cells on a gel (Page 1, Column 2, Paragraph (i.e., ¶) 0008, Lines 2-4 and Claim 54) in form of cell aggregates, the aggregates may be formed on a variety of substrates including scaffolds (Page 4, Column 2, ¶0049, Lines 3-

- 5) and/or gels, wherein gels are of collagen, or polyglycolic acid (Page 5, Column 2, continuation of ¶ 0052, Lines 1-4 and Claims 56 and 65);
- said cell aggregates having a diameter in range of about 100 μm to 3 millimeters (Page 4, Column 2, ¶ 0047, Lines 6-7);
 - said cell aggregates are made of a single cell type or multiple cell types (Page 4, Column 2, ¶ 0047, Lines 1-5; Claim 63);
 - the thickness of cell and/or matrix layers range from 2 μm to 3 mm (Page 7, Column 1, ¶ 0061, Lines 1-13);
 - the three dimensional structure comprised of cell aggregates comprises alternating layers of cell aggregates and the matrix material, wherein said layers are 2 to multiple layers (Page 5, Column 1, continuation of ¶ 0050, Lines 1-4; Figure 7; Page 7, Column 1, continuation of ¶ 0060, Lines 7-18);
 - the limitations in Claims 64-65 that said biocompatible matrix is present as a separate layer beneath cell aggregates or above the cell aggregates or between the cell aggregate layers (Page 5, Column 1, continuation of ¶ 0050, Lines 1-4).

Thus, as discussed supra, Boland et al., teach a composition comprising a three dimensional layered structure/composition comprising an array of viable cells in form of aggregates\ that can be formed on a variety of materials including gels and scaffolds which is the limitation in instantly presented Claim 52. Please note an array is a non-random predetermined pattern. Boland et al., teach the limitation in instantly presented Claim 57, because Boland et al., further teach that the diameter of said aggregates varies in the range of about 100 μm to 3 mm which range encompasses the diameter of about 100 μm to about 600 μm ; and the limitation in instantly presented Claims 59-60 because said aggregates/arrays are made of single or multiple types of cells. Boland et al., also teach the limitation in instantly presented Claim 61 because the thickness of each of the matrix and/or cell aggregate layer ranges from 2 μm to 3 mm, which range encompasses the thickness of about 100 μm to about 600 μm . Boland et al., also teach the limitations in Claims 64-65 because at Page 5, Boland et al. further teach that said biocompatible matrix is present as a separate layer beneath cell aggregates or above the cell aggregates or between the cell aggregate layers. Since the biocompatible matrix layers are made of matrices

comprised of e.g., collagen or agarose or glycolic acid or any polymer thereof, Boland et al. also teach the limitation in Claim 66 that the biocompatible matrix in one layer comprises a biocompatible matrix different than the one in the other layer.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made and one having ordinary skill in the art at the time of the claimed invention would have been motivated to modify/combine the teachings from Furukawa et al., according to those from Boland et al. to obtain a three dimensional layered structure comprised of living cell aggregates embedded in a biocompatible matrix in a non-random predetermined pattern;

because Boland et al. teach a composition comprising a three dimensional layered structure/composition comprising an array of viable cells in form of aggregates that can be formed on a variety of materials including gels and scaffolds. Boland et al., further teach that the diameter of said aggregates varies in the range of about 100 μm to 3 mm which range encompasses the diameter of about 100 μm to about 600 μm and additionally teach said aggregates/arrays are made of single or multiple types of cells. Boland et al., also teach the thickness of each of the matrix and/or cell aggregate layer ranges from 2 μm to 3 mm, which range encompasses the thickness of about 100 μm to about 600 μm and further teach that said biocompatible matrix is present as a separate layer beneath cell aggregates or above the cell aggregates or between the cell aggregate layers. Additionally, since the biocompatible matrix layers are made of matrices comprised of e.g., collagen, agarose, glycolic acid, or any polymer thereof, Boland et al., also teach that the biocompatible matrix in one layer comprises a biocompatible matrix different than the one in the other layer.

From the teachings of the references cited supra, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

15. Claims 54-55 are rejected under 35 U.S.C. § 103 (a) as obvious over combined teachings from Furukawa et al (2001. Tissue-engineered skin using aggregates of normal human skin

fibroblasts and biodegradable material J Artif. Organs, Volume 4, Pages 353-356) in view of Boland et al., (US 2004/0237822 A1) and Roth et al. (2004. Inkjet printing for high-throughput cell patterning. Biomaterials, Volume 25, Pages 3707–3715) as applied to Claims 52-53 and 56-63 above and further in view of Mizumoto et al (1999. Formation of cylindrical multicellular aggregate (cylindroid) and expression of liver specific functions of primary rat hepatocytes. Cytotechnology, Volume 31, Pages 69–75).

Claim 54 recites an additional limitation that cell aggregates are cylindrical.

The three dimensional layered structure claimed in instantly presented Claims 54-55 is interpreted to be a composition comprised of different components.

Mizumoto et al., teach cylindrical multicellular aggregate (i.e., cylindroid) of primary rat hepatocytes and further teach that said cylindroids are approximately 200 μm –500 μm in diameter and 500 μm –2 mm in length (abstract, Lines 1-5).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made and one having ordinary skill in the art at the time of the claimed invention would have been motivated to modify/combine the teachings from Furukawa et al., according to those from Boland et al., and Mizumoto et al., to obtain a three dimensional layered structure comprised of living cell aggregates embedded in a biocompatible matrix in a non-random predetermined pattern, wherein said aggregates are spheroids and cylindroids, **because Boland et al.** teach a composition comprising a three dimensional layered structure/composition comprising an array of viable cells in form of aggregates\ that can be formed on a variety of materials including gels and scaffolds. Boland et al., further teach that the diameter of said aggregates varies in the range of about 100 μm to 3 mm which range encompasses the diameter of about 100 μm to about 600 μm and additionally teach said aggregates/arrays are made of single or multiple types of cells. Boland et al., also teach the thickness of each of the matrix and/or cell aggregate layer ranges from 2 μm to 3 mm, which range encompasses the thickness of about 100 μm to about 600 μm and further teach that said biocompatible matrix is present as a separate layer beneath cell aggregates or above the cell aggregates or between the cell aggregate

layers. Additionally, since the biocompatible matrix layers are made of matrices comprised of e.g., collagen, agarose, glycolic acid, or any polymer thereof; Boland et al., also teach that the biocompatible matrix in one layer comprises a biocompatible matrix different than the one in the other layer and Mizumoto et al., teach cylindrical multicellular aggregate (i.e., cylindroid), said cylindroids are approximately 200 μm – 500 μm in diameter and 500 μm – 2 mm in length.

From the teachings of the references cited supra, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

16. For reasons aforementioned, no Claims are allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:00 A.M. to 5:30 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Jon Weber, can be reached on (571)-272-0025 Monday through Thursday 7:30 A.M. to 6:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). Alternatively, status inquiries should be directed to the receptionist whose telephone number is (703) 308-0196.

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